PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (see an example) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Assessing the short-term outcomes of a community-based intervention for overweight and obese children: The MEND 5-7 programme.
AUTHORS	Smith, Lindsey; Chadwick, Paul; Radley, Duncan; Kolotourou, Maria; Gammon, Catherine; Rosborough, Jennifer; Sacher, Paul

VERSION 1 - REVIEW

REVIEWER	Carolyn Summerbell Professor of Nutrition Durham University, UK	
REVIEW RETURNED	I have no conflicts of interest. 27-Jan-2013	

THE STUDY	This article reports on a service evaluation. As such, there isn't a 'research' question. The authors present changes over time in body weight and various other measures, in young children who took part in a weight management service called MEND 5-7. It is unsurprising that mean BMI decreased a little in the obese children whose parents actively opted them into the MEND 5-7 weight loss programme. The fact that the provision of this type of programme is rare in the UK, and many health professionals support it's use, means that it is highly valued by many users.
	As stated above, the article reports a service evaluation, but it is written (at least in parts) like a feasibility study. The authors mention feasibility on more than one occasion. A feasibility study would include some estimate of cost of the service, and also the feasibility of it's roll out and delivery. There is no data on cost in the article, nor any process evaluation, qualitative data, or fidelity assessment. As such, the findings from this service evaluation are of limited use in helping commissioners of service evaluate its potential for roll-out.
RESULTS & CONCLUSIONS	The results presented in this article, which reports a service evaluation, are credible and well presented.
REPORTING & ETHICS	I do not know of any standard and recommended reporting statement or checklist for service evaluations.
	The authors state that their 'research' received no specific grant from any funding source. It would have been more useful if they listed the various funding sources (for both the prgramme and the researchers time) which they had received.

REVIEWER	Assoc Prof Tim Gill
	Principal Research Fellow
	Boden Institute of Obesity, Nutrition, Exercise and Eating Disorders

	Medical Foundation Building K25 University of Sydney NSW 2006 Australia
	I have no competing interests in relation to the review of this manuscript
REVIEW RETURNED	07-Feb-2013

THE STUDY	The conclusions of the paper indicate the acceptability of the program to families but there appears to be no assessment of the acceptability to families apart from completion or attendance rates. The methods are generally well described but the selection of the certain measures is poorly justified and validated questions or instruments have not been used: In particular physical activity and fruit and vegetable consumption
	are assessed using very short, non validated questions. Simple relatively short but validated instruments or questions are available to asses these variables A 25 item strength and difficulty questionnaire is used to asses child behaviour but the paper does not set out ant rationale for using this tool and does not indicate any identified link between weight and the behaviours assesses or any proposed impact of the program on these behaviours. The reference cited in the manuscript for this instrument also appears to be inappropriate.
	The section on data cleaning refers to the removal of outliers by visual observation of the data. This process was poorly described and there was no objective criteria for defining outlying values.
RESULTS & CONCLUSIONS	The discussion acknowledges the limitations of the study design but these limitations should result in more conservatism when discussing the outcomes of the program in practice. The study design was non-experimental, the study participants were self-selected and only 62% completed the post program measurements. Clearer acknowledgment of this limitations should occur when comparing the weight reduction achieved here with the weight status outcomes reported from RCT assessments of other early childhood weight management programs (and based on an intention to treat analysis).
REPORTING & ETHICS	There is no indication in the manuscript that ethics approval was sought and obtained for this study.
GENERAL COMMENTS	This program focuses on children aged 5-7 and the introduction raises the issue of age appropriate interventions. However, there is no discussion of the importance or rationale for weight management programs addressing this age group and why there has been limited focus on this age group previously in the UK.
	The statements about recommended strategies within the sentence beginning on line 38 on page 4 should be referenced. The statements around the benefits of group interventions in the sentence beginning on line 15 and line on page 6 should be referenced

REVIEWER	Beatrice Nojilana
	Senior scientist
	South African Medical research Council
	South Africa

	I have no conflict of interest to the study
REVIEW RETURNED	08-Feb-2013

THE STUDY	I did not get much of statistics details for the research.
GENERAL COMMENTS	Title: Assessing the short term effects of a scalable, community-based intervention for overweight and obese children: The MEND 5-7 programme. Suitability and importance of paper: This paper aimed to report the outcomes from UK service level delivery of MEND 5-7 (Mind, Exercise, NutritionDo it!) a multicomponent community-based healthy lifestyle intervention designed for overweight and obese children aged 5-7 years and their families. Importance for the readership: In the face of current efforts to curb the rapid increase of non-communicable diseases, this paper has some public health importance. In addition, the premise that parents are receptive to and participated in the programme has assisted with the behavioural change that may have promoted healthy weight in there young children.
	General comment: 1. Although significant impact was demonstrated the results are limited by the small number of participants, one should advise that caution is needed in interpreting these results. Pre and post- test does not allow to test whether this difference would have occurred in the absence of interventions. It is also important to gather more information on the processes of intervention. Is there anything that could have been done which increased the intervention's impact? Are there alternatives for the apparent impact of intervention? These issues needed to be explored as well. 2. One more limitation is that the cost benefit was not evaluated since scaling up intervention will have broad policy implications. 3. Differences in ethnicities and socio-economic positions are likely to limit the scale up. 4. Drop-out how were the missing data treated in the statistical analysis? 5. Lengthy explanation of the programme less info on statistical methods. References and literature review: Satisfactory

VERSION 1 – AUTHOR RESPONSE

Reviewer: Carolyn Summerbell

1. This article reports on a service evaluation. As such, there isn't a 'research' question. The authors present changes over time in body weight and various other measures, in young children who took part in a weight management service called MEND 5-7.

No action required

2. It is unsurprising that mean BMI decreased a little in the obese children whose parents actively opted them into the MEND 5-7 weight loss programme. The fact that the provision of this type of programme is rare in the UK, and many health professionals support it's use, means that it is highly valued by many users.

No action required

3. As stated above, the article reports a service evaluation, but it is written (at least in parts) like a

feasibility study. The authors mention feasibility on more than one occasion. A feasibility study would include some estimate of cost of the service, and also the feasibility of its roll out and delivery. There is no data on cost in the article, nor any process evaluation, qualitative data, or fidelity assessment. As such, the findings from this service evaluation are of limited use in helping commissioners of service evaluate its potential for roll-out.

The intent of the manuscript was not to present a feasibility study of intervention roll-out and any inference of this is a misrepresentation on our part. We have revised the language accordingly to remove any such inference and also highlighted the need for this research in the conclusion.

4. The results presented in this article, which reports a service evaluation, are credible and well presented.

No action required

5. I do not know of any standard and recommended reporting statement or checklist for service evaluations.

No action required

6. The authors state that their 'research' received no specific grant from any funding source. It would have been more useful if they listed the various funding sources (for both the programme and the researchers time) which they had received.

The details requested have been included.

Reviewer: Assoc Prof Tim Gill

- 1. The conclusions of the paper indicate the acceptability of the program to families but there appears to be no assessment of the acceptability to families apart from completion or attendance rates. Comments on acceptability have been removed from the abstract and main conclusion.
- 2. The methods are generally well described but the selection of the certain measures is poorly justified and validated questions or instruments have not been used.

 In particular physical activity and fruit and vegetable consumption are assessed using very short, non validated questions. Simple relatively short but validated instruments or questions are available to asses these variables.

We are unaware of any validated instruments for physical activity and dietary consumption assessment suitable for implementation in community settings by non-researchers under service level conditions. Available methods that we know of are prohibitive by their participant burden, cost and/or application (e.g. web-based, multiple daily time points).

We feel our position is supported by the 'Measuring diet and physical activity in weight management interventions' document produced by the UK National Obesity Observatory in March 2011. This report identifies a shortlist of practical and validated questionnaires for the assessment of physical activity and diet, to support public health practitioners to evaluate weight management interventions. The derived list, based on best available evidence from three separate systematic reviews, includes only three questionnaires for physical activity assessment and six for dietary assessment in children. Of these, none of the physical activity and only three of the dietary questionnaires cover the age range in the current study. Of these three, two do not measure the actual amount and type of food consumed and the other is prohibitive by its participant burden and application.

The measures of fruit and vegetable intake used in the study were from a battery of instruments used in published research on the influence of family mealtimes affecting children's vegetable consumption (Sweetman et al., 2011) developed by the research group at Cancer Research UK's Health Behaviour Research Centre at UCL, where the second author has the role of honorary Clinical Research Fellow.

This is an area of our work we constantly find challenging. If the reviewer knows of measures that may suitable for future use we would be extremely grateful if they would provide us with this information.

3. A 25 item strength and difficulty questionnaire is used to assess child behaviour but the paper does not set out any rationale for using this tool and does not indicate any identified link between weight and the behaviours assessed or any proposed impact of the program on these behaviours. The reference cited in the manuscript for this instrument also appears to be inappropriate. Child obesity has been reliably associated with elevated levels of psychological distress in the published literature (Vander Wal and Mitchell, 2011). The SDQ is the most widely used empirically validated psychometric instrument for the screening and measurement of clinically significant emotional distress. Most expert committees recommend that the goals of paediatric obesity treatment programmes should include the reduction of psychosocial morbidity that is reliably associated with obesity (NICE, 2006; American Academy of Paediatrics, Barlow et al., 2007). For this reason it is appropriate to include a reliable measure of psychological distress. The text of the paper has been amended to provide a rationale for inclusion.

Thank-you for spotting the incorrect reference - this mistake has been amended.

4. The section on data cleaning refers to the removal of outliers by visual observation of the data. This process was poorly described and there was no objective criteria for defining outlying values.

Due to the data being collected under service level conditions by non-researchers we felt it important to try and establish outliers caused by human error, such as errors in data collection, recording, or entry.

There is much controversy over what constitutes an outlier. The majority of parametric outlier tests look at some measure of the relative distance of a particular data point to the mean of all the data points and assesses the probability that a particular piece of data occurred by chance. However, outliers can greatly influence summary statistics. This is one reason why eliminating data that for instance exceeds two or three standard deviations, may not be a good, or even a reasonable, decision rule.

For this reason visual inspection of scatterplots and histograms of key anthropometric variables of change were conducted to assess for obvious signs of measurement error.

This enabled us to triangulate possible error and identify observations that appear to be inconsistent with other observations in the data set. This procedure suggested 7 changes in height were obvious outliers. To assess whether these were true measurement error, the degree of change in the outliers was compared to reference guides for the average degree of change in height for children of this age and height over an equal time period, which was 1.2 cm for both boys and girls. A decision was then made to exclude these 7 data sets due to biologically unlikely increases in height of over 5.5 cm.

If unable to correct the data, as in our case, conceptually, there are strong arguments for removal of outliers of this nature as they do not represent valid population data points. Benefits can also be empirically demonstrated – both correlations and t-tests showing significant changes in statistics as a function of removal of outliers, and in the overwhelming majority of analyses accuracy of estimates are enhanced. In this instance removal of outliers resulted in deletion of BMI z-score change values that were inflated due to large increases in height, meaning that the method used to clean the data did not contribute to an artificial inflation of treatment effect.

We believe our mistake in the paper was not providing sufficient detail of the exclusion criteria in such a way that would reliably allow similar exclusion from any subsequent attempt to recreate our analysis in independent data. For this reasons we have included additional information in the statistics section of the paper.

- 5. The discussion acknowledges the limitations of the study design but these limitations should result in more conservatism when discussing the outcomes of the program in practice. The study design was non-experimental, the study participants were self-selected and only 62% completed the post program measurements. Clearer acknowledgment of this limitation should occur when comparing the weight reduction achieved here with the weight status outcomes reported from RCT assessments of other early childhood weight management programs (and based on an intention to treat analysis). The discussion and conclusion have been revised to remove suggestion of cause-and-effect, provide a more conservative interpretation of out findings and highlight the requirement for more experimental research.
- 6. There is no indication in the manuscript that ethics approval was sought and obtained for this study. As requested by the journal guidelines a statement regarding ethical approval is included at the end of the manuscript. The position stated is not personal judgement, it is the formal response previously received by Duncan Radley from a NHS ethics committee when undertaking similar service level evaluations.
- 7. This program focuses on children aged 5-7 and the introduction raises the issue of age appropriate interventions. However, there is no discussion of the importance or rationale for weight management programs addressing this age group and why there has been limited focus on this age group previously in the UK.

It is unclear to us why there has been limited focus on this age group previously in the UK and would hesitate to speculate. We feel that the fact that there is a gap, is in itself sufficient rationale for evaluating an intervention that is mapped to Key Stage 1 criteria and adds to the understanding of the outcomes that is possible to achieve for overweight and obese children in this age range in a UK setting. For clarity we have included this latter point in the introduction.

8. The statements about recommended strategies within the sentence beginning on line 38 on page 4 should be referenced.

The appropriate reference has been included.

9. The statements around the benefits of group interventions in the sentence beginning on line 15 and line on page 6 should be referenced

The above comment is incomplete. However, we believe we have added the appropriate references regarding groups as requested on page 6.

Reviewer: Beatrice Nojilana

- 1. I did not get much of statistics details for the research.

 Having received statistic advice we are confident that the appropriate analysis has been undertaken.
- 2. Suitability and importance of paper: This paper aimed to report the outcomes from UK service level delivery of MEND 5-7 (Mind, Exercise, Nutrition...Do it!) a multicomponent community-based healthy lifestyle intervention designed for overweight and obese children aged 5-7 years and their families. No action required
- 3. Importance for the readership: In the face of current efforts to curb the rapid increase of non-communicable diseases, this paper has some public health importance. In addition, the premise that

parents are receptive to and participated in the programme has assisted with the behavioural change that may have promoted healthy weight in there young children.

No action required

General comment:

- 4. Although significant impact was demonstrated the results are limited by the small number of participants, one should advise that caution is needed in interpreting these results. Pre and post-test does not allow to test whether this difference would have occurred in the absence of interventions. It is also important to gather more information on the processes of intervention. Is there anything that could have been done which increased the intervention's impact? Are there alternatives for the apparent impact of intervention? These issues needed to be explored as well. We feel this point is similar to those made by the editor and Professor Gill. To address this issue we have removed the cause-and-effect language throughout the manuscript, been conservative when discussing the outcomes of the programme, extended the limitations section and amended the conclusion.
- 5. One more limitation is that the cost benefit was not evaluated since scaling up intervention will have broad policy implications.

We fully agree that a cost benefit analysis is important and necessary. However we believe this is a separate piece of work and falls outside the aims of the current manuscript.

- 6. Differences in ethnicities and socio-economic positions are likely to limit the scale up. We have highlighted in the conclusion that further research is required to investigate this area.
- 7. Drop-out how were the missing data treated in the statistical analysis? The intention of the manuscript is to report outcomes for children who completed the intervention. We therefore do not feel it is appropriate to include missing data in an intention to treat analysis and addressed our aim reporting only paired data.
- 8. Lengthy explanation of the programme less info on statistical methods? We feel that there is already sufficient description of the programme having provided more information than commonly reported for this type of manuscript. If there are any specific areas you feel more details are required then we would be happy to add further information.

Regarding the statistical methods, we do not believe these to be verbose, but rather the necessary length to adequately describe the procedures undertaken. Please note we have been asked to add further description of methods by one of the other reviewers.

References and literature review: Satisfactory No action required